



Application No. 09/940,377
Patent & Trademark Office dated: November 10, 2003
Attorney Docket No: 4441-0006

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11/14/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First-Named Inventor : BARDY, Gust H
Serial No. : 09/940,377
Filing Date : August 27, 2001
Title : METHOD OF INSERTION AND IMPLANTATION OF
IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR
CANISTERS
Customer No. : 22440
Confirmation No. :
Group Art Unit : 3762
Examiner : DROESCH, Kristin L

Commissioner for Patent
PO Box 1450
Alexandria, VA 22313-01450

CERTIFICATE OF MAIL UNDER 37 CFR §1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service via First Class mail service in a post-paid envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on 11.12.2003.


HUNTER, Belinda J.

INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 CFR §§1.56, 1.97 AND 1.98

SIR:

Pursuant to the duty disclosure under 37 CFR §§1.56, 1.97 and 1.98, applicant submits herewith an *Information Disclosure Statement* along with the *List of Cited References* (substitute Form PTO-1449).

References A1 - A31 on the enclosed substitute Form PTO-1449 are incorporated by reference within the specification of the subject patent application. For the Examiner's

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convenience, applicant has indicated on said form the page numbers and line numbers that correspond to the specification.

Inasmuch as the present application has not yet received a first Office Action on the merits in accordance with 37 CFR §1.97(b)(3), this information is believed to be timely filed. Accordingly, consideration of the enclosed references and entry into the record are respectfully requested.

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It is believed that no fee for filing this *Information Disclosure Statement* is now due. If it is determined, however, that any fee is required, the Commissioner is hereby authorized to charge any such fee to Deposit Account No. 07-1730. A duplicate of this sheet is enclosed herewith.

Dated: November 10, 2003
New York, New York

Respectfully submitted,

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**INFORMATION DISCLOSURE
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Sheet: 1 of 10

Application Number: 09/940,377
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 Examiner Name: DROESCH, Kristin L
 Attorney Docket No: 4441-0006

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**INFORMATION DISCLOSURE
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Sheet: 2 of 10

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Attorney Docket No: 4441-0006

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Substitute for form PTO-1449		Application Number: 09/940,377
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Filing Date: August 27, 2001
		First-Named Inventor: BARDY, Gust H
		Group Art Unit: 3762
		Examiner Name: DROESCH, Kristin L
Sheet: 3 of 10		Attorney Docket No: 4441-0006

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Examiner Initials	Cite No.	Document Number with kind code if known	Publication Date MM-DD-YYYY	Name of Patentee/Applicant	Comments on Relevance
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EB	WO 02/24275 A3	03.21.2002	Cappato et al	ISR PCT/IB03/04516		
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OTHER PRIOR ART - - NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, symposium, etc), date, page(s), volume-issue, all citation information				T ²
	ED	International Search Report dated 03.26.2002, PCT/US01/29168 filed 09.14.2001, published as WO 02/22208 on 03.21.2002, "Subcutaneous Only Implantable Cardioverter Defibrillator & Optional Pacer", Inventors: Bardy et al				
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	EN	International Search Report dated 02.20.2003, PCT/IB02/03447 filed 08.27.2002; published as WO 03/018110 on 03.06.2003, "Subcutaneous Electrode for Transthoracic Conduction with Improved Installation Characteristics", Inventors: Bardy et al				
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	EP	International Search Report dated 02.20.2003, PCT/IB02/03501 filed 08.26.2002; published as WO 03/018112 on 03.06.2003, "Subcutaneous Electrode for Transthoracic Conduction with Low-Profile Installation Appendage and Method of Doing Same", Inventors: Bardy et al				

Examiner Signature:	Date Considered:
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Substitute for form PTO-1449		Application Number: 09/940,377
INFORMATION DISCLOSURE		Filing Date: August 27, 2001
STATEMENT BY APPLICANT		First-Named Inventor: BARDY, Gust H
Sheet: 7 of 10		Group Art Unit: 3762
		Examiner Name: DROESCH, Kristin L
		Attorney Docket No: 4441-0006

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS		
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, symposium, etc), date, page(s), volume-issue, all citation information
	EQ	International Search Report dated 02.20.2003, PCT/IB02/03502 filed 08.23.2002; published as WO 03/018127 on 03.06.2003, "Subcutaneous Electrode for Transthoracic Conduction with Insertion Tool", Inventors: Bardy et al
	ER	International Search Report dated 02.20.2003, PCT/IB02/03525 filed 08.23.2002; published as WO 03/018130 on 03.06.2003, "Subcutaneous Electrode for Transthoracic Conduction with Highly Maneuverable Insertion Tool", Inventors: Bardy et al
	ES	International Search Report dated 03.06.2003, PCT/IB02/04513 filed 10.28.2002; published as WO 03/039663 on 05.15.2003, "Method and Apparatus for Inducing Cardiac Fibrillation", Inventors: Ostroff et al
	ET	International Search Report dated 03.28.2003, PCT/IB03/04454 filed 10.28.2002, published as WO 03/041278 on 05.15.2003, "Low Power A/D Converter", Inventors: Ostroff
	EU	International Search Report dated 04.16.2003, PCT/IB03/04546 filed 10.28.2002, published as WO 03/039656 on 05.15.2003, "Subcutaneous Electrode with Improved Contact Shape for Transthoracic Conduction", Inventors: Bardy et al
	EV	International Search Report dated 04.16.2003, PCT/IB03/04490 filed 10.28.2002, published as WO 03/039665 on 05.15.2003, "Monophasic Waveform for Anti-Tachycardia Pacing for a Subcutaneous Implantable Cardioverter-Defibrillator", Inventors: Cappato
	EW	International Search Report dated 04.16.2003, PCT/IB03/04498 filed 10.28.2002, published as WO 03/039666 on 05.15.2002, "Current Waveforms for Anti-Bradycardia Pacing for a Subcutaneous Implantable Cardioverter-Defibrillator", Inventors: Ostroff et al
	EX	International Search Report dated 04.16.2003, PCT/IB03/04507 filed 10.28.2002, published as WO 03/039667 on 05.15.2003, "Current Waveforms for Anti-Tachycardia Pacing for a Subcutaneous Implantable Cardioverter-Defibrillator", Inventors: Ostroff et al
	EY	International Search Report dated 04.16.2003, PCT/IB03/04516 filed 10.28.2002, published as WO 03/039668 on 05.15.2003, "Flexible Subcutaneous Implantable Cardioverter-Defibrillator", Inventors: Ostroff et al
	EZ	International Search Report dated 04.16.2003, PCT/IB03/04543 filed 10.28.2002, published as WO 03/039669 on 05.15.2003, "Monophasic Waveform for Anti-Bradycardia Pacing for a Subcutaneous Implantable Cardioverter-Defibrillator", Inventors: Bardy et al
	FA	International Search Report dated 04.23.2003, PCT/IB02/04497 filed 10.28.2002, published as WO 03/039649 on 05.15.2003, "Packaging Technology For Non-Transvenous Cardioverter-Defibrillator Devices", Inventors: Ostroff et al
	FB	International Search Report dated 04.23.2003, PCT/IB02/04515 filed 10.28.2002, published as WO 03/039651 on 05.15.2003, "Subcutaneous Implantable Cardioverter-Defibrillator Employing A Telescoping Lead", Inventors: Erlinger et al
	FC	International Search Report dated 04.25.2003, PCT/IB02/04475 filed 10.28.2002, published as WO 03/039647 on 05.15.2003, "Optional Use of a Lead For a Unitary Subcutaneous Implantable Cardioverter-Defibrillator", Inventors: Bardy et al
	FD	International Search Report dated 05.08.2003, PCT/IB02/04514 filed 10.28.2002, published as WO 03/039650 on 05.15.2003, "H-Bridge With Sensing Circuit", Inventors: Rissman et al
	FE	International Search Report dated 10.01.2003, PCT/US03/10666 filed 04.04.2003, published as WO 03/089059 on 10.30.2003, "Subcutaneous Cardiac Stimulator Device With Small Contact Surface Electrodes", Inventors: Bardy et al
	FF	International Search Report dated 05.08.2003, PCT/IB02/04476 filed 10.28.2002, published as WO 03/039648 on 05.15.2003, "Defibrillation Pacing Circuitry", Inventors: Ostroff

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Substitute for form PTO-1449		Application Number: 09/940,377
		Filing Date: August 27, 2001
INFORMATION DISCLOSURE		First-Named Inventor: BARDY, Gust H
STATEMENT BY APPLICANT		Group Art Unit: 3762
Sheet: 8 of 10		Examiner Name: DROESCH, Kristin L
		Attorney Docket No: 4441-0006

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, symposium, etc), date, page(s), volume-issue, all citation information	T ²
	FG	International Preliminary Examination Report dated 11.20.2002, PCT/US01/29168 filed 09.14.2001, published as WO 02/22208 on 03.21.2002, "Subcutaneous Only Implantable Cardioverter Defibrillator & Optional Pacer", Inventors: BARDY et al;	
	FH	International Preliminary Examination Report dated 12.18.2002, PCT/US01/29106 filed 09.14.2001, published as WO 02/24275 on 03.28.2002, "Subcutaneous Only Implantable Cardioverter Defibrillator & Optional Pacer", Inventors: BARDY et al	
	FI	International Preliminary Examination Report dated 09.02.2003, PCT/IB02/03447 filed 08.27.2002; published as WO 03/018110 on 03.06.2003, "Subcutaneous Electrode for Transthoracic Conduction with Improved Installation Characteristics", Inventors: Bardy et al	
	FJ	International Preliminary Examination Report dated 09.02.2003, PCT/IB02/03452 filed 08.23.2002; published as WO 03/018119 on 03.06.2003, "Insulated Shell for Subscutaneously Implantable Cardioverter-Defibrillator Canister", Inventors" Bardy et al	
	FK	International Preliminary Examination Report dated 09.02.2003, PCT/IB02/03453 filed 08.23.2002; published as WO 03/018122 on 03.06.2003, "Duckbill-Shaped Implantable Cardioverter-Defibrillator Canister and Method of Use", Inventors: Bardy et al	
	FL	International Preliminary Examination Report dated 09.02.2003, PCT/IB02/03467 filed 08.26.2002; published as WO 03/018123 on 03.06.2003, "Canister Designs for Implantable Cardioverter-Defibrillators", Inventors: Bardy et al	
	FM	International Preliminary Examination Report dated 09.02.2003, PCT/IB02/03469 filed 08.26.2002; published as WO 03/018124 on 03.06.2003, "Biphasic Waveform for a Subcutaneous Implantable Cardioverter-Defibrillator", Inventors: Bardy et al	
	FN	International Preliminary Examination Report dated 09.02.2003, PCT/IB02/03484 filed 08.26.2002; published as WO 03/018126 on 03.06.2003, "Cardioverter-Defibrillator having a Focused Shocking Area and Orientation Thereof", Inventors: Bardy et al	
	FO	International Preliminary Examination Report dated 09.02.2003, PCT/IB02/03501 filed 08.26.2002; published as WO 03/018112 on 03.06.2003, "Subcutaneous Electrode for Transthoracic Conduction with Low-Profile Installation Appendage and Method of Doing Same", Inventors" Bardy et al	
	FP	International Preliminary Examination Report dated 09.02.2003, PCT/IB02/03502 filed 08.23.2002; published as WO 03/018127 on 03.06.2003, "Subcutaneous Electrode for Transthoracic Conduction with Insertion Tool", Inventors: Bardy et al	
	FQ	International Preliminary Examination Report dated 09.02.2003, PCT/IB02/03503 filed 08.26.2002; published as WO 03/018128 on 03.06.2003, "Power Supply for a Subcutaneous Implantable Cardioverter-Defibrillator", Inventors: Bardy et al	
	FR	International Preliminary Examination Report dated 09.02.2003, PCT/IB02/03522 filed 08.26.2002; published as WO 03/018129 on 03.06.2003, "Biphasic Waveform for Anti-Bradycardia Pacing for a Subcutaneous Implantable Cardioverter-Defibrillator", Inventors: Bardy et al	
	FS	International Preliminary Examination Report dated 09.02.2003, PCT/IB02/03525 filed 08.23.2002; published as WO 03/018130 on 03.06.2003, "Subcutaneous Electrode for Transthoracic Conduction with Highly Maneuverable Insertion Tool", Inventors: Bardy et al	
	FT	International Preliminary Examination Report dated 09.02.2003, PCT/IB02/03488 filed 08.26.2002, published as WO 03/018120 on 03.06.2003, "Curved Implantable Cardioverter-Defibrillator Canister", Inventors: Bardy et al	
	FU	Written Opinion dated 09.10.2002, PCT/US01/29168 filed 09.14.2001, published as WO 02/22208 on 03.21.2002, "Subcutaneous Only Implantable Cardioverter Defibrillator & Optional Pacer", Inventors: Gust H BARDY et al	

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Substitute for form PTO-1449		Application Number: 09/940,377
INFORMATION DISCLOSURE		Filing Date: August 27, 2001
STATEMENT BY APPLICANT		First-Named Inventor: BARDY, Gust K
Sheet: 9 of 10		Group Art Unit: 3762
		Examiner Name: DROESCH, Kristin
		Attorney Docket No: 4441-0006

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS		
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, symposium, etc), date, page(s), volume-issue, all citation information
	FV	Written Opinion dated 09.03.2002, PCT/US01/29106 filed 09.14.2001, published as WO 02/24275 on 03.28.2002, "Unitary Subcutaneous Only Implantable Cardioverter Defibrillator & Optional Pacer", Inventors: BARDY et al
	FW	Written Opinion dated 05.12.2003, PCT/IB02/03447 filed 08.27.2002; published as WO 03/018110 on 03.06.2003, "Subcutaneous Electrode for Transthoracic Conduction with Improved Installation Characteristics", Inventors: Bardy et al
	FX	Written Opinion dated 05.12.2003, PCT/IB02/03452 filed 08.23.2002; published as WO 03/018119 on 03.06.2003, "Insulated Shell for Subscutaneously Implantable Cardioverter-Defibrillator Canister", Inventors" Bardy et al
	FY	Written Opinion dated 05.12.2003, PCT/IB02/03453 filed 08.23.2002; published as WO 03/018122 on 03.06.2003, "Duckbill-Shaped Implantable Cardioverter-Defibrillator Canister and Method of Use", Inventors: Bardy et al
	FZ	Written Opinion dated 05.12.2003, PCT/IB02/03467 filed 08.26.2002; published as WO 03/018123 on 03.06.2003, "Canister Designs for Implantable Cardioverter-Defibrillators", Inventors: Bardy et al
	GA	Written Opinion dated 05.12.2003, PCT/IB02/03469 filed 08.26.2002; published as WO 03/018124 on 03.06.2003, "Biphasic Waveform for a Subcutaneous Implantable Cardioverter-Defibrillator", Inventors: Bardy et al
	GB	Written Opinion dated 05.12.2003, PCT/IB02/03484 filed 08.26.2002; published as WO 03/018126 on 03.06.2003, "Cardioverter-Defibrillator having a Focused Shocking Area and Orientation Thereof", Inventors: Bardy et al
	GC	Written Opinion dated 05.12.2003, PCT/IB02/03501 filed 08.26.2002; published as WO 03/018112 on 03.06.2003, "Subcutaneous Electrode for Transthoracic Conduction with Low-Profile Installation Appendage and Method of Doing Same", Inventors" Bardy et al
	GD	Written Opinion dated 05.12.2003, PCT/IB02/03502 filed 08.23.2002; published as WO 03/018127 on 03.06.2003, "Subcutaneous Electrode for Transthoracic Conduction with Insertion Tool", Inventors: Bardy et al
	GE	Written Opinion dated 05.12.2003, PCT/IB02/03503 filed 08.26.2002; published as WO 03/018128 on 03.06.2003, "Power Supply for a Subcutaneous Implantable Cardioverter-Defibrillator", Inventors: Bardy et al
	GF	Written Opinion dated 05.12.2003, PCT/IB02/03522 filed 08.26.2002; published as WO 03/018129 on 03.06.2003, "Biphasic Waveform for Anti-Bradycardia Pacing for a Subcutaneous Implantable Cardioverter-Defibrillator", Inventors: Bardy et al
	GG	Written Opinion dated 05.12.2003, PCT/IB02/03525 filed 08.23.2002; published as WO 03/018130 on 03.06.2003, "Subcutaneous Electrode for Transthoracic Conduction with Highly Maneuverable Insertion Tool", Inventors: Bardy et al
	GH	Written Opinion dated 05.12.2003, PCT/IB02/03488 filed 08.26.2002, published as WO 03/018120 on 03.06.2003, "Curved Implantable Cardioverter-Defibrillator Canister", Inventors: Bardy et al
	GI	Journal of the American Medical Association (JAMA), Vol 214, No 6, 1123pp, Nov 9, 1970, "Completely Implanted Defibrillator", an editorial comment by JC SCHUDER PhD,
	GJ	Amer Soc Trans Artif Int Organs, Vol XVI, 1970, 207-212pp, "Experimental Ventricular Defibrillation With An Automatic & Completely Implanted System", by JC SCHUDER PhD et al
	GK	Archives of Internal Medicine (Specialized Journal of the AMA), Vol 127, Feb 1971, Letters to the Editor 317pp, "Standby Implanted Defibrillators", an editorial comment by JC SCHUDER PhD

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Sheet: 10 of 10

Application Number: 09/940,377
Filing Date: August 27, 2001
First-Named Inventor: BARDY, Gust H
Group Art Unit: 3762
Examiner Name: DROESCH, Kristin L
Attorney Docket No: 4441-0006

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, symposium, etc), date, page(s), volume-issue, all citation information	T ²
	GL	Journal of the American Medical Association (JAMA), Vol 213, 615-616pp, 1970, "Automatic Detection & Defibrillation of Lethal Arrhythmias--A New Concept", by MIRKOWSKI et al	
	GM	IEEE Transactions on Bio-Medical Engineering, Vol BME-18, No 6, Nov 1971, 410-415pp, "Transthoracic Ventricular Defibrillation In The Dog With Truncated and Untruncated Exponential Stimuli", by JC SCHUDER PhD et al	
	GN	IEEE Engineering in Medicine & Biology Society Magazine – Proceedings of the Annual International Conference of the IEEE Orlando, FL, copyright 1991, Vol 13, 1674-1676 pp, "Analog to Digital Conversion Techniques in Implantable Devices", by RA WALTERS et al Comments on Relevance: ISR PCT/IB03/04454	
	GO	PACE, Vol 16, Part I, Jan 1993, 95-124pp, "The Role Of An Engineering Oriented Medical Research Group In Developing Improved Methods & Devices For Achieving Ventricular Defibrillation: The University Of Missouri Experience", by JC SCHUDER PhD	
	GP	Journal of Cardiovascular Electrophysiology, Vol 12, No 3, March 2001, 356-360pp, Copyright 2001, by Future Publishing Company Inc, Armonk-NY 1050-0418, "Nonthoracotomy Implantable Cardioverter Defibrillator Placement In Children", by Rainer GRADAUS MD et al	
	GQ	Journal of Cardiovascular Electrophysiology, Vol 12, No 3, March 2001, 361-362pp, Copyright 2001, by Future Publishing Company Inc, Armonk-NY 1050-0418, "Implantable Defibrillators In Children: From Whence to Shock", by Richard A FRIEDMAN MD et al	
	GR	Springer-Verlag, Berlin-Germany, copyright 1991, 784-786pp, "Halbleiter-Schaltungstechnik", by U. TIETZE and Ch. SCHENK Comments on Relevance: ISR PCT/IB03/04454	Y
	GS	"Onset & Stability for Ventricular Tachyarrhythmia Detection in an Implantable Pacer-Cardioverter-Defibrillator", IEEE Computers in Cardiology, 1987, Vol 0276-6574, 167-170pp, by Walter H OLSON et al; Comments on Relevance: Specification Page 15, Line 19-22	

Examiner
Signature:

Date
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